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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,138	05/09/2001	Geert Maertens	2752-43	4881

23117 7590 11/17/2003

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/17/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/851,138

Applicant(s)

MAERTENS ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-70 is/are pending in the application.
- 4a) Of the above claim(s) 64-66 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63 and 67-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/836,075.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: sequence comparison data sheet

DETAILED ACTION

Petition under Rule 181

The petition under Rule 181 filed on 04/17/2003 has been acknowledged. The application will be sent back to the special program of the Technical Center for decision on petition after the office action is mailed out.

Election/Restrictions

1. In the amendment of paper No. 14, filed on May 28, 2003, Applicants canceled claims 1-62 and amended claims 63. Furthermore, Applicants request Office to reconsider the election/restriction requirement and rejoin claims 64, 65 and 67 with elected group I, claims 63 and 68-69. Applicants' request has been respectfully considered. Claim 67 is rejoined because it was directed to the method of making a polypeptide encoded by the nucleic acid of claim 63. However, claims 64 and 65 are not rejoined for the reason set forth below.
2. In the petition under rule 118, Applicants argue that the subject matter of the present claims has been allowed and issued in U.S. patent No. 6,180,768. As Patent Office has already examined and allowed the presently claimed subject matter, and further examination of the present claimed invention should not placed an undue burden on the examiner.
3. Applicants also insisted since claim 65 was amended and SEQ ID NO: 50 has been changed to SEQ ID NO: 52, the restriction requirement is therefore moot in view of the amendment.
4. Applicants further argue that the SEQ ID NO: 138, 155, 174, 190 and 207 of claim 65 are all segment of SEQ ID NO: 52, which are all unique to SEQ ID NO: 52 and the HCV type 10 isolate such that these sequences are included in allowed claim 4 subpart (ii) of US Patent No. 6,180,768.
5. Applicants also asserted that claims 63 and 65 are related and should not be restricted because SEQ ID NO: 52 is an amino acid sequence encoded by the nucleic acid sequence of SEQ ID NO: 51 as recited by claim 63. A search of claim 63 of SEQ ID NO: 51 would appear to require a search of the subject matter of claim 65, i.e. a nucleotide sequence encoding SEQ ID NO: 52.

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6. Applicants' argument has been respectfully considered. However, it is not found persuasive because the amendment of claim 65 does not indicate that the polynucleotide of claim 63 is the same as the polynucleotide of claim 65.

7. US Patent No. 6,180,768, which is US Application SN. 08/836,075 has been reviewed by the examiner. It is noticed that this Patent has been withdrawn from the publication and currently are under reexamination. The previously allowed subject matter in claim 4 only includes the polynucleotide encoding an HCV polyprotein comprising the amino acid sequence of SEQ ID NO: 52. There is no indication that SEQ ID NO: 138, 155, 174, 190 or 207 is examined and allowed in the claim 4.

8. More importantly, the polynucleotide sequence encoding the polyprotein of SEQ ID NO: 52 was compared with nucleic acid sequence of SEQ ID NO: 51, it was found that SEQ ID NO: 52 is not encoded by the nucleic acid sequence of SEQ ID NO: 51 (Please see the sequence analysis data).

9. Therefore, Applicants' argument is incorrect. The Applicants should not mislead the Office because the nucleic acid molecule of SEQ ID NO: 51 is not the same nucleic acid molecule that encoding the amino acid sequence of SEQ ID NO: 52. Therefore, claim 65 is rejoined with claim 63 because they are directed to different DNA molecules (Please see the sequence analysis data).

10. Further, Office needs to point out that while the polynucleotide sequence encoding the amino acid sequence of polyprotein SEQ ID NO: 138, 155, 174, 190 and 207 is a segment of SEQ ID NO: 52, The claimed polynucleotide sequence encoding an amino acid sequence comprising SEQ ID NO: 138, 155, 174, 190 or 207 does not only read on the same polynucleotide sequence encoding the polyprotein comprising the amino acid sequence of SEQ ID NO: 52. Because claim 65 uses an open language to describe the claimed polypeptide, Office interpreted the claims broadly as any polynucleotide encoding an HCV polyprotein as long as it contains the sequence of 138, 155, 174, 190 or 207. Applicants' attention is directed to the MPEP 2111.03 regarding the interpretation of claim, which use an open language of "comprising".

11. *The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the*

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claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

12. Especially, HCV is a quasispecies RNA virus, which is able to mutate rapidly and automatically in adapting to the environments, a single isolated HCV strains even can generate more than a hundred clones in the most genetically heterogeneous region and each clone exhibits different immunogenecityies. Therefore, despite that SEQ ID NO: 52 includes the SEQ ID NO: 138, 155, 174, 190 or 207, the SEQ ID NO: 138, 155, 174, 190 and 207 may not only exist in SEQ ID NO: 52.

13. Regarding claims 64 and 66-70, Applicants argue that the amino acid residues recited in claim 64 are recited in the allowed claim 3 of US Patent No. 6,180,768. The subject matter of pending claims 66-70 are believed to be found in the previous allowed claims 7-11 of US Patent No. 6,180,768. Accordingly, the pending claims are submitted to be allowed and as the subject matter has been previously examined by the Patent Office in one Application, the restriction requirement should be withdrawn.

14. Claims 3 and 7-11 of US Patent No. 6,180,768 have been carefully reviewed. It was noticed that claimed subject matters recited claims 3 and 7-11 are not exactly the same as the current claims 64 and 66-70. For instance, claim 3 is a dependent claim of claim 1, which limits the claimed amino acid mutation to the polynucleotide of claim 1. In contrast, claim 64 is an independent claim, the claimed polynucleotide is broadly directed to any polynucleotide having at least one amino acid mutation of claim 64. For the same notion, claims 7-11 of US Patent No. 6,180,768 are also dependent claims of claims 1-5, which limit the claimed polypeptide to the sequences of claims 1-5. However, the polypeptide of claim 66 is not only directed to the claim 63, but also to claim 65, which include many other polynucleotide sequences that are not examined in the parental application.

15. For the purpose of clarification on the record, the newly rejoined claims in different groups are summarized:

- I. Claims 63, 67-69, drawn to a HCV polynucleic acid molecule encoded by SEQ ID NO: 51 and method for using the same.

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- II. Claims 64, 67-69, drawn to a HCV polynucleic acid molecule having a particular amino acid residue mutation or and method for using the same.
 - III. Claims 65, 67-69, drawn to another HCV polynucleic acid molecule encoded another HCV polyprotein comprising amino acid sequence SEQ ID NO: 52 and its fragment thereof.
 - IV. Claims 66 and 70, drawn to a polypeptide of HCV.
- Claims 63 and 67-69 are considered before the examiner.

Response to Amendment

This is a response to the amendment, paper No. 14, filed 06/28/03. Claims 1-62 are have been canceled. Claim 63 is amended. Claims 63-70 are pending. Claims 63 and 67-79 are considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

- 16. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 17. Claims 63 and 67-69 are still rejected under 35 U.S.C. 112, second paragraph on the sat ground as stated in the previous Office Action, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention
- 18. Claim 63 is still unclear in that the metes and bounds of "a part of said polynucleic acid" are not defined. Applicants argue that claim 2 of US patent No. 6,180,768 was allowed previously, a person with ordinary skill will not question about the metes and bounds of the claimed language.
- 19. Applicants' argument has been respectfully considered; however, it is not found persuasive because the US patent No. 6,180,768 is withdrawn for the publication, the claimed subject is not longer effective as a patentable subject matter. The SEQ ID NO: 51 has 447

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nucleic acids, which part of the sequence is intended? Is 10 nucleic acids intended? Or 50 nucleic acids intended? This affects the dependent claims 67-69.

Conclusion

No claims are allowed.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

November 16, 2003


JAMES HOUSEL 11/17/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Tue Nov 4 14:00:40 2003

us-09-ε

NAME: KAMMERER, PATRICIA A.
REGISTRATION NUMBER: 29,775
REFERENCE/DOCKET NUMBER: INNS:004
INFORMATION FOR SEQ ID NO: 51:
SEQUENCE CHARACTERISTICS:
LENGTH: 447 base pairs
TYPE: nucleic acid
STRANDEDNESS: single
TOPOLOGY: linear
MOLECULE TYPE: CDNA
HYPOTHETICAL: NO
ANTI-SENSE: NO
US-08-836-075A-51

Alignment Scores:

Pred. No.:	6.9e-82	Length:	447
Score:	791.00	Matches:	146
Percent Similarity:	97.99%	Conservative:	0
Best Local Similarity:	97.99%	Mismatches:	3
Query Match:	99.12%	Indels:	0
DB:	3	Gaps:	0

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QY	1	AspGlyIleAsnPheAlaThrGlyAsnLeuProGlyCysSerPheSerIlePheLeuLeu	20
Db	1	GACGGATTAATTTTCGCAACAGGGAATTTACCTGGTTGCTTTCTCTATCTCTCTCTG	60
QY	21	AlaLeuPheSerCysLeuLeuThrProThrAlaGlyLeuGluTyrArgAsnAlaSerGly	40
Db	61	GCTTTGTTCTCATGCTTGCTTACACCCACAGCGGGCTGGAGTACCGTAATGCTCCGGA	120
QY	41	LeuTyrMetValThrAsnAspCysSerAsnGlySerIleValTyrGluAlaGlyAspIle	60
Db	121	CTCTACATGGTAATAACGACTGCAGTACGGTAGTATCGTGTAGAGCGCGGGATATT	180
QY	61	IleLeuHisLeuProGlyCysValProCysValArgSerGlyAsnThrSerArgCysTrp	80
Db	181	ATCCTCCACTTACCTGGCTGTGTCCTGCTGCTGCTGCTGCTGCTGCTGCTGCTGCTG	240
QY	81	IleProValSer***ThrValAlaValLysSerProCysAlaAlaThrAlaSerLeuArg	100
Db	241	ATCCCTGTGAGCCCVACCGTCGCCGTGAAGTCGCCCTGCGCGCCACCGCTCTCTCCG	300
QY	101	ThrHisValAspMetMetVal***AlaAlaThrLeuCysSerAlaLeuTyrValGlyAsp	120
Db	301	ACGCACGTGGATATGATGCTGGGCGGCCACCTATGCTCAGCTCTCTACGTAGAGAC	360
QY	121	LeuCysGlyAlaLeuPheLeu***GlyGlnGlyPheSerTrpArgHisArgGlnHisTrp	140
Db	361	CTTTGTGGAGCGCTATTCTTTGTGGGCGAGGGTTCTCATGGAGACATCCCGCATTGG	420
QY	141	ThrValGlnAspCysAsnCysSerIle	149
Db	421	ACTGTCCAGGACTGCACACTGTTCCATC	447